SUPPORTING STATEMENT
FOR
Latex Condoms; User Labeling-, Expiration Dating
(21 CFR 801.435)
OMB No. 0910-0352

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) is requesting OMB approval for device labeling regulations contained within 21 CFR 801.435. FDA has amended labeling requirements to add 21 CFR 801.435, a requirement for expiration date labeling for latex condoms, to protect the public health and minimize the risk of device failure. This requires latex condoms to be labeled with an expiration date, which must be supported by data from quality control tests. These tests demonstrate physical and mechanical integrity of three random lots of the same product stored under accelerated and real time conditions and which expose the product to varying conditions that age latex. Sections 519, 502(a), 704, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (sections 21 U.S.C. 360(i), 352(a), 374, and 371) establish the statutory authority to collect information under this regulation. Section 519 describes recordkeeping requirements, 501(a) misbranding of devices, 704 authority for inspecting manufacturing facilities, and 701 general administrative procedures, including regulations and hearings.

The recording of shelf life testing by condom manufacturers is used to support the expiration dating on the labeling of latex condoms. Information concerning the usable life of latex condoms is necessary to allow lay users to use these products safely by avoiding use of products that may have degraded. The effectiveness of latex condoms as a barrier to the transmission of infectious agents is dependent upon the integrity of the latex material. Degradation of latex film products like latex condoms occurs when latex is exposed to various types of environmental conditions normally experienced in product use, shipment, or storage situations. Degradation may result in bursts, rips, tears, or seepage that allows the transmission of infectious agents. The information and records generated under this regulation will be used to establish an expiration date that will inform consumers when the product should no longer be used.

Section 510(h) (Attachment A) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360(h)) requires that condom manufacturers as device manufacturers be inspected at least once in a two year period. During that inspection, FDA inspectors will review the test records used to support the expiration date in order to ensure that the expiration date is accurate. This recordkeeping requirement is approved under 0910-0073.

The following is a description of information collection requirements in 801.435.

801.435 - Third Party Disclosure

Condom manufacturers are required to include an expiration date in the labeling. The expiration date must be supported by data from quality control tests demonstrating physical and mechanical integrity of three random lots of the same product which were stored under accelerated and real time conditions.

2. By Whom and for What Purpose the Information is to be Used

Condom manufacturers will use the information collected from the testing to establish the expiration date to be printed on the labeling and purchasers will use the information collected to determine likely effectiveness.

3. Consideration of Information Technology

Manufacturers may use any appropriate technology to develop and disseminate the required labeling.

4. Efforts to Identify Duplication and Similar Information Already Available

The information required by the expiration dating for latex condoms regulation is available, only from the manufacturer. Information from one manufacturer is not available from another. FDA is the only Federal agency responsible for the collection of such information, and charged with the responsibility of regulating establishments that manufacture medical devices for introduction into interstate commerce. Therefore, no other existing record keeping system can be used or modified.

5. Impact on Small Business or Other Small Entities

The requirements imposed by this information collection are applied equally to all firms, regardless of their size. This regulation requires physical and mechanical integrity tests. Because condom manufacturers routinely conduct such tests on their products, the regulation would affect manufacturers only by requiring additional tests following storage of the products under established conditions. The final rule that created this information collection required a labeling change and the 180-day time period between the publication date and effective date of the final rule allowed most manufacturers to exhaust their existing supply of labels. Accordingly, the rule did not have significant economic impact on small entities, and the requirements of this information collection are not expected to have a significant impact on small entities.

6. Consequences of Collecting the Information Less Frequently and Technical or Legal Obstacles

The labeling requires an expiration date to appear on the primary packaging (i.e., the individual package), as well as higher levels of labeling, such as the case containing individually packaged products to ensure visibility. Under section 502(a) of the act (21 U.S.C. 352(a)), a device is misbranded if its labeling is false or misleading in any particular. The failure to reveal material

facts, such as when .the condom may have degraded, is false and misleading labeling. Section 502(f) (21 U.S.C. 352(f)) requires that labeling must bear adequate directions for use. Adequate directions for use means adequate directions under which a lay person can use a device safely and for the purpose for which it is intended (see 21 CFR 801.4 and 801.5). Information concerning latex condom shelf life is necessary to allow lay users to use the product safely by avoiding use of products that may have degraded. Failure to include expiration date information would render the product misbranded under section 502(a) and (f) of the act.

There are not technical or legal obstacles to the collection of this information.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

The information collection in the labeling regulation is consistent with 5 CFR 1320.5, with the exception of section 801.435(j) which requires testing data to be held for the expected life of the condom. This requirement is necessary since many condoms normally are intended to be used for more than three years and are labeled so. FDA must have access to this type of information in order to conduct long range investigations.

8. Consultation Outside, the Agency

Notice has been published in the Federal Register on Friday, June 23, 2000 (65 FR 39150) soliciting comments on this information collection (See attachment B).

The Agency has had numerous contacts with manufacturers of condoms through a variety of mechanisms including during GMP inspections, with FDA reviewers during the 501(k) application process and with involvement in standards development with ASTM and ISO. These standards groups have recently drafted new protocols and analytical methods for assessing the shelf life of condoms that may eventually supersede the methods contained in 21 CFR 801.437. These draft protocols and methods are currently being reviewed and commented by FDA.

This data has also been reviewed by investigators during every comprehensive GMP inspection of a condom manufacturer that took place in the last 3 years. Furthermore, FDA discusses stability study testing and protocols with manufacturers as it relates to new products for which 510(k)'s are submitted.

9. Payments or Gifts to Respondents

There is no payment or gift provided to respondents of this information collection.

10. Assurance of Confidentially Provided to Respondent

The labeling required by this rule is, by its nature, public information.

11. Sensitive Questions

The information required by this collection does not include questions about sexual behavior, attitude, religious beliefs or other matters that are commonly considered private or sensitive in nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

Respondents to this collection of information are domestic and foreign Condom manufacturers.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL BURDEN FOR REPORTING/DISCLOSURE					
21 CFR	No of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Respondent	Total Hours
801.435	45	1	45	96	4,320

FDA performed several steps to derive the burden hour estimates. FDA started with an estimate of the number of respondents, which was determined through consultations with FDA and industry staff. FDA arrived at the number of affected domestic establishments by reviewing the FDA database of registered medical device manufacturers. The estimate of the number of domestic establishments is 5. FDA determined the number of affected foreign establishments by reviewing the database of registered medical device manufacturers and counting the number of foreign manufacturers. The estimate of the number of foreign firms that export condoms to the United States is 40. Consequently, FDA estimated the number of condom manufacturers subject to the additional required testing to be 45 respondents.

FDA estimates that a respondent would take 10 hours to check the 200 individual data points that it needs to check in order to complete the tests. FDA had originally estimated that each respondent would perform 12 tests on each type of condom. The 12 tests consisted of tests on three lots of product conducted at the time of production, after storage for 7 days, 90 days, and at five years. Based upon public comments, the agency had revised its estimates in three significant ways. First, the estimate for the number of tests to be run was doubled in response to comments stating FDA underestimated the burden because the tests would be required for variations on a standard condom. Second, the estimate for the number of tests was again doubled in response to comments stating that tests should be conducted after storage for I year, 2 years, 3 years, and 4 years, in order to accurately determine shelf life through real-time testing. Third, because the tests would be conducted at regular intervals over five years, the burden estimate has been annualized over that five-year period. In sum, the agency has revised its estimate of the number of tests to be performed, representing a four-fold increase in burden hours, but has annualized the

burden over five years, Therefore, the estimated total hours of reporting/disclosure is estimated to be 4,320 annually.

Cost to Respondents

The costs to respondents is $90,720, This is based on 45 manufacturers each of which has 96 hours of burden (4,320 total hours) to gather data required from testing. Most condoms are now produced outside of the United States, and engineer/scientists in charge of the testing and labeling procedures are estimated to be paid approximately $21.00 an hour.

13. Capital and Start up Costs and Operating and Maintenance Costs

There are no capital costs and or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA estimates that the inspection of the expiration date testing would take an inspector up to one hour to review, and would be included as part of the regular inspection. For that reason the cost would be minimal. FDA estimates that the average FDA inspector or lab technician is paid between $17 to $44 an hour.

15. Explanation of Program Changes or Adjustment

The burden that is reported for this collection has decreased slightly since this collection was last approved. Originally, an estimate of 53 foreign manufacturers was used to calculate burden estimates for this collection. Currently, due to consolidation of firms and normal business attrition, the total number of foreign manufacturers is estimated to be 40. The total number of manufacturers, therefore, decreased from 58 to 45 (as domestic manufacturers remained at 5 firms). Total burden hours, therefore, declined 1,248 hours, from 5,568 to 4,320 total burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration is Inappropriate

Currently, FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Currently, FDA is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.

B - Collections of Information Employing Statistical Methods

There are no statistical methods being employed in this collection of information.

List of Attachments:

Attachment A – Federal Food, Drug, and Cosmetic Act
Attachment B - Federal Register 60 Day Notice Friday June 23, 2000 (65 FR 39150)